K113689

MAY - 4 2012

510(k) Summary
(as required by 807.92(c)

Submitter of 510(k): Dukal Corporation
2 Fleetwood Court
Ronkonkoma, NY 11779

Contact Person: Patrick J. Lamb
VP International/Operations Manager

Date of Summary: December 5, 2011

Trade/Proprietary Name: Dukal Sterile Lubricating Jelly

Classification Name: Lubricant, Patient

Product Code: KMJ

Intended Use:

The Dukal Sterile Lubricating Jelly is a medical device intended for medical purposes, to lubricate body orifices to facilitate entry of diagnostic devices when a sterile field is required.

Device Description:

The Dukal Sterile Lubricating Jelly is a clear, greaseless, water soluble jelly.

Device Packaging:

A typical packaging configuration for the Dukal Sterile Lubricating Jelly
Is a 2.7g or 5gm foil packs and 2oz or 4oz tubes. Other sizes may become available.

Predicate Device:

Dynarex Sterile Lubricating Jelly, 510(k) K092488 is manufactured for Dynarex 10 Glenshaw St. Orangeburg, NY 10962.

Substantial Equivalence:

The Dukal Sterile Lubricating Jelly provides effective lubrication during the insertion of diagnostic and therapeutic devices into the body orifices. Its function and performance are similar to the predicate device as presented in this 510(k).

Safety and Effectiveness of the device:

This device is as safe and effective as the predicate device cited above based on the following:

Summary comparing technological characteristics with other predicate device: Dukal Sterile Lubricating Jelly is similar in terms of intended use and technological characteristics to predicate devices reviewed as a lubricating jelly to facilitate the entry of a diagnostic or therapeutic device. The device is substantially equivalent with respect to indications for use and other characteristics to predicate devices in terms of section 510(k) substantial equivalency.

Please find below a tabulated comparison supporting that this device is substantially equivalent to the predicate device in commercial distribution.

Comparative Chart

Technological Characteristics	Dukal	Dynarex
Purified Water	Yes	Yes
Carbomer Thickeners	Yes	Yes
Methylparabens	Yes	Yes
Labeled Water Soluble	Yes	Yes
Labeled Non Staining	Yes	Yes
Labeled Alcohol and fragrance free	Yes	Yes
Container Material	Plastic/Film Laminate	Plastic/Film Laminate
Sterile	Yes	Yes
Physical Tests		
Biocompatibility Testing	ISO 10993	ISO 10993
	In-Vitro Cytotoxicity -Pass	In-Vitro Cytotoxicity -Pass
	Implantation-Pass	Implantation-Pass
	Irritation & Hypersensitivity -Pass	Irritation & Hypersensitivity -Pass
	Systemic Toxicity - Pass	Systemic Toxicity - Pass
In-Vitro Cytotoxicity		

Sterilization:

The Dukal Sterile Lubricating Jelly is sterilized by gamma irradiation under parameters that have been validated according to ISO/AAMI 11137 requirements (sterilization of health care products – requirements for validation and routine control radiation sterilization) with SAL of 10^{-6}

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Patrick J. Lamb
Vice President International/Operations Manager
Dukal Corporation
2 Fleetwood Court
Ronkonkoma, New York 11779

MAY - 4 2012

Re: K113689
Trade/Device Name: Dukal Sterile Lubricating Jelly
Regulation Number: 21 CFR 880.6375
Regulation Name: Patient Lubricant
Regulatory Class: II
Product Code: KMJ
Dated: April 17, 2012
Received: April 25, 2012

Dear Mr. Lamb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name: Dukal Sterile Lubricating Jelly

Indications for use:

The Dukal Sterile Lubricating Jelly is a medical device intended for medical purposes, to lubricate body orifices to facilitate entry of diagnostic devices when a sterile field is required.

Prescription Use_____ AND/OR Over-The Counter Use_X__
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number:_____

5/3/12

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113689